STATE OF MICHIGAN

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS OFFICE OF FINANCIAL AND INSURANCE REGULATION

Before the Commissioner of Financial and Insurance Regulation

File No. 122112-001

In the matter of XXXXX

Petitioner

UnitedHealthcare Insurance Company

Respondent

Issued and entered this 17TH day of October 2011 by R. Kevin Clinton Commissioner

ORDER

I. PROCEDURAL BACKGROUND

On June 29, 2011, XXXXX (Petitioner) filed a request for external review with the Commissioner of Financial and Insurance Regulation under the Patient's Right to Independent Review Act (PRIRA), MCL 550.1901 *et seq.* After a preliminary review of the documentation submitted, the Commissioner accepted the case for external review on July 7, 2011.

The Commissioner immediately notified UnitedHealthcare Insurance Company (United) of the external review and requested the information used in making its adverse determination. United's response was received on July 7, 2011.

Because medical issues are involved, the Commissioner assigned the case to an independent review organization which provided its analysis and recommendations in a report dated July 21, 2011. (A copy of the complete report is being provided to the parties with this Order.)

II. FACTUAL BACKGROUND

The Petitioner is insured under a group medical policy (the policy) underwritten by United.

Petitioner has a history of gastroesophageal reflux disease. On June 21, 2010, Petitioner underwent a surgical procedure known as a transoral incisionless fundoplication, or "TIF". United denied coverage, ruling that the procedure was unproven for the treatment of the Petitioner's condition.

The Petitioner appealed the denial through United's internal grievance process. United affirmed its claim denial and issued its final adverse determination letter dated June 6, 2011.

III. ISSUE

Did United correctly deny coverage for the Petitioner's surgery of June 21, 2010?

IV. ANALYSIS

Petitioner's Argument

In her request for review, Petitioner wrote:

United Healthcare was called and notified of the intent to perform a transoral incisionless fundoplication. This procedure was explained in detail to XXXXX at UHC who gave authorization for the procedure saying no preauthorization was needed. I had the T.I.F. on 6-21-10 with no payment for the surgery, have gone through all the appeal processes and still have not had my surgeon's claim paid. I had the surgery based on the approval of UHC.

Respondent's Argument

In its final adverse determination of June 6, 2011, United reported the conclusions of its medical director:

Your Plan has no benefit for unproven services. I reviewed your letter of appeal and supporting documentation. The preponderance of clinical evidence in the prevailing published peer-reviewed medical literature is insufficient and inadequate to conclude that procedure 43499 - Transoral Incisionless Fundoplication is an effective treatment for diagnosis that has a beneficial effect on health outcomes. Therefore, CPT code 43499 - Transoral Incisionless Fundoplication is an unproven service and not eligible for reimbursement. . . .

Commissioner's Review

The policy (p. 25) excludes coverage for experimental, investigational or unproven services:

E. Experimental or Investigational or Unproven Services

Experimental or Investigational and Unproven Services and all services related to Experimental or Investigational and Unproven Services are excluded. The fact that an Experimental or Investigational or Unproven Service, treatment, device or pharmacological regimen is the only available treatment for a particular condition will not result in Benefits if the procedure is considered to be Experimental or Investigational or Unproven in the treatment of that particular condition. . . .

The question of whether the Petitioner's surgery was experimental, investigational or unproven in the treatment of the Petitioner's condition was presented to an independent medical review organization (IRO) for analysis, as required by section 11(6) of the Patient's Right to Independent Review Act. The IRO reviewer is a physician in active practice who is certified by the American Board of Surgery and is a Fellow of the American College of Surgeons and the International College of Surgeons. The reviewer is also published in peer-reviewed medical literature. The IRO reviewer's report includes the following analysis and conclusion:

The most recently published literature regarding the transoral incisionless fundoplication (TIF) procedure support that this procedure is not experimental or investigational for a subset of patients who are candidates for surgical fundoplication; specifically, patients who either cannot obtain complete relief from standard PPI therapy or who wish to avoid a lifetime dependence on such medications, and present with a 2 centimeter (cm) or smaller hiatal hernia.

* * *

The literature references include outcomes data on more than 200 patients with up to two-year follow up. These data support that the TIF procedure has withstood appropriate peer-reviewed scrutiny and is a safe and efficacious procedure for appropriately selected patients. Additionally, there is adequate long-term data to support the application of TIF in selected clinical circumstances. . . .

* * *

The published position statement of The American Society of General Surgeons represents evidence-based conclusions and support for the application of transoral fundoplication in the setting of refractory GERD and a hiatal hernia of 2 cm or less.

The Commissioner is not required in all instances to accept the IRO's recommendation. However, the IRO recommendation is afforded deference by the Commissioner. In a final order which rejects an IRO recommendation, the Commissioner must cite "the principal reason or reasons why the commissioner did not follow the assigned independent review organization's recommendation." MCL 550.1911(16)(b). The IRO's analysis is based on extensive experience, expertise, and professional judgment. The Commissioner can discern no reason why that judgment should be rejected in the present case.

The Commissioner accepts the IRO's recommendation that transoral incisionless fundoplication is not an experimental, investigational or unproven treatment for the Petitioner's condition. Therefore, the procedure is a covered benefit under the certificate.

V. ORDER

The Commissioner reverses UnitedHealthcare Insurance Company's June 6, 2011, final adverse determination. United shall provide coverage for Petitioner's surgery within 60 days of the date of this Order and shall, within seven (7) days of providing coverage, submit to the Commissioner proof it has implemented this Order.

To enforce this Order, the Petitioner may report any complaint regarding the implementation to the Office of Financial and Insurance Regulation, Health Plans Division, toll free 877-999-6442.

This is a final decision of an administrative agency. Under MCL 550.1915, any person aggrieved by this Order may seek judicial review no later than 60 days from the date of this Order in the circuit court for the county where the covered person resides or in the circuit court of Ingham County. A copy of the petition for judicial review should be sent to the Commissioner of Financial and Insurance Regulation, Health Plans Division, Post Office Box 30220, Lansing, MI 48909-7720.